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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/560,475 04/28/00 GREENSPAN

D 028870-178

EXAMINER

HM12/0928

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ART UNIT

PAPER NUMBER

1615

DATE MAILED:

09/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/560,475

Applicant(s)

GREENSPAN ET AL.

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1615

DETAILED ACTION

Receipt is acknowledged of the Declaration and Fee, received February 1, 2001.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,707,829 to Jacobs *et al.* in view of US Patent 5,236,458 to Ducheyne *et al.*

Jacobs *et al.* disclose therapeutic, diagnostic, and research utilities for polynucleotides and proteins (c 1, l 5-8). Jacobs *et al.* teach that their composition may be contain a pharmaceutically acceptable carrier, and any necessary excipients and additives (c 16, l 25-33). Further, at column 19, lines 18-57, Jacobs *et al.* discloses the choices in matrix materials for the composition, including bioglass. Additionally, Jacobs *et al.* teach that their composition can contain a wide variety of proteins, and growth factors, such as TGF-alpha (c 20, l 26). More specifically, at column 16, lines 6-24, Jacobs *et al.* teach that their protein of the invention can exhibit one of the following effects: killing bacteria, viruses, fungi, effecting body characteristics, effecting the processing dietary fat, protein, or carbohydrate, effecting behavioral characteristics, and providing analgesic or other pain reducing effects, among others. This is evidence that

Art Unit: 1615

the composition disclosed by Jacobs *et al.* can be used for many different purposes.

Lastly, Jacobs *et al.* teaches at column 10, lines 51-58, that the protein of their invention may be one which suppresses chronic or acute inflammation, such as, that associated with Crohn's disease or resulting from overproduction of cytokines such as TNF or IL-1. It is the position of the examiner that this disclosure reads on applicant's method claims.

Jacobs *et al.* does not go into detail regarding the empirical makeup of the bioglass used as a matrix material in their composition. However, a skilled practitioner would look to other, relevant teachings in order to discover the well makeup of bioglass. Ducheyne *et al.* is relied upon for teaching the specifics of bioglass. At column 4, lines 21-25, Ducheyne *et al.* teach that bioglass contains 5-14% Na₂O, 0-12% P₂O₅, 49-57% SiO₂, and 33% CaO and CaF₂.

One of ordinary skill in the art would have been motivated to combine the teachings of Jacobs *et al.* and Ducheyne *et al.* in order to create a successful pharmaceutical formulation. The motivation to combine lies in Jacobs *et al.*'s teaching that bioglass would be a suitable matrix material for their invention, and Ducheyne *et al.* is simply used to clarify the specific makeup of bioglass. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Art Unit: 1615

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

aep
September 27, 2001


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600